Remarks

This is in response to the Office Action mailed May 5, 2006 in the above-identified patent application. Claims 1, 3-5 and 7-12 are pending in the present application, of which claims 1, 8 and 12 are independent.

In that Office Action, the Examiner (1) rejected claims 1, 3, 5 and 7 were rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,761,704 to Crawford, (2) rejected claim 4 under 35 U.S.C. 103(a) as being obvious over Crawford in view of US 6,726,649 to Swenson, and (3) rejected claims 8-12 under 35 U.S.C. 103(a) as being obvious over US 5,495,855 to Dudar et al. in view of Crawford.

In response, applicants have canceled claims 1-7, 9, 10 and 12. Claim 8 has been amended to include, among other things, the subject matter of canceled claims 9 and 10, to distinguish over the cited references.

Turning first to the rejection of Claims 8-12, Claim 8 has been amended to recite, among other things, a one-piece connector unit for attachment to the barrel of a sample tube receiver, and a cover assembly. Amended Claim 8 further recites the unit having a first end terminating in a blunted piercing tip, and a second end including a hollow needle terminating in a sharpened piercing tip. Removable covers enclose the blunted piercing tip and the sharpened piercing member. Amended Claim 8 further recites that each of the covers include an open and a closed end, wherein the open ends face one another and wherein the open ends of the covers are adjacent to and substantially abutting each other.

Applicant's respectfully submit that Dudar does not teach or suggest the claimed invention for several reasons. First, Dudar does not teach a one-piece connector as presently claimed. Instead, Dudar teaches a multi-component adapter with one end that includes a needle, and a second end that includes a cannula. The cannula is a blunt cannula or a luer, in which another cannula or a second needle is attached. The attachment of another component would be necessary to allow, for example, means for accessing a source of blood through an injection site on a donor. See col. 4, lines 23-30. The fact that Dudar discloses inserting the blunt cannula end 26 into a further component is, in fact, more like the prior art shown in Figures 1A-C of the present application. (See below for a more detailed discussion of Figures 1A-C).

Specifically, the one-piece connector unit of the present invention is ready to be used for its intended purpose. Thus, when using the presently claimed invention, some of the steps required in Dudar (as well as in the referenced Figures 1A-C of the prior art) can be eliminated. In particular, the step of attaching a second, separately provided cannula or needle in order to convert the blunt end into a usable piercing end is eliminated. When the user removes the end caps of the one-piece connector unit of the present invention, the user can quickly assemble a sampling device with a cannula already in place. No separate attachment of a cannula member is required. In addition, fewer assembled parts of such one-piece connector unit results in less waste in terms of disposable end caps for the different pieces. It is exactly this multi-step assembly described in Dudar that the present invention was intended to overcome. For this

reason, Applicants respectfully submit that Dudar does not teach or suggest a one-piece connector as required by amended Claim 8.

Second, as acknowledged by the Examiner, Dudar does not disclose a one-piece connector unit having a cover assembly as presently claimed. That is, Dudar does not teach or suggest a cover assembly having two removable covers, nor does it disclose a flexible sleeve covering the sharpened piercing tip. Specifically, Dudar does not disclose a flexible sleeve enclosing a hollow needle, nor does it disclose a removable cover enclosing a blunted piercing tip and a removable cover enclosing a sharpened piercing member wherein each of the covers comprise an open and a closed end, wherein the open ends face one another and wherein the open ends of the covers are adjacent to and substantially abutting each other, as required by amended Claim 8. As acknowledged by the Examiner, Dudar only discloses that one needle (needle 12) may be enclosed by a removable cover or shield.

Further, Applicants respectfully submit that it would not have been obvious to one of ordinary skill in the art to combine the teaching of Dudar with the teaching of Crawford to arrive at the claimed invention for several reasons. First, the disclosure of Crawford makes a passing reference to providing two needle covers, but there is no detailed or meaningful discussion of this particular feature. Specifically, in col. 8, line 4, and col. 8 line 15, the specification makes reference to needle covers, but to such a brief extent that they are both designated as "not shown". One is left to speculate, even after reading the disclosure of Crawford, the location of the covers relative to the

disclosed structure and relative to each other. As such, only the impermissible use of hindsight, using the teaching of the present application, would lead one of ordinary skill in the art to combine the references cited by the Examiner to arrive at the claimed invention.

In any event, if one is to consider the disclosure of Crawford, it does not teach the needle cover assembly as presently claimed. For example, the open end of any needle covers (not shown), if attached to the needle assembly disclosed in Crawford, could not possibly abut each other as required by amended Claim 8. Instead, the open end of one cover would engage shoulder 16, while the open end of another cover would engage threaded portion 14, with the open ends separated by the central disc portion of hub assembly 20. (See Figure 1, for example). Again, one must assume what the position of the covers would be if attached to the disclosed structure, but it is clear that they could not possibly achieve the abutting position as required by amended Claim 8.

As described in further detail of the present specification, there are several advantages to providing needle covers that abut each other, for example, so that the open ends in an abutting relationship may be sealed together by a breakable tamper-evident band 95 (See Figure 2) before use. (Also see specification page 9, para. 43). For at least these reasons, Applicants submit that Claim 8 and its respective dependent claim is not obvious over Dudar in view of Crawford.

Similarly, the prior art shown in Applicant's own application does not teach or suggest a one piece connector unit as presently claimed. Similar to the assembly of the

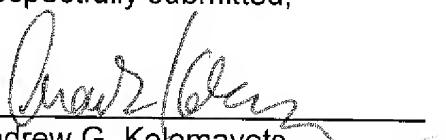
device discussed above with respect to Dudar, Figures 1A-C (labeled as "Prior Art") of the present application show a multi-component sampling device. The multi-component device shown in Figures 1A-C require various steps of assembly by the end user before it can be used for its intended purpose. Specifically, the multi-component luer adapter 12 includes a needle 20 secured onto one end of a hub 22, and a luer end 32 on the other end of the hub 22. Luer end 32 must be provided with another piercing member to allow for penetration of an access site of a container from which samples are to be drawn. Accordingly, a separately provided cannula 34 or other piercing member is required to convert the luer end 32 into a piercing end capable of piercing the access site (such as a septum) of a container. See specification, page 6, para. 29. Once again, it is exactly this multi-step assembly that the present invention was intended to overcome.

As described above with respect to Dudar, the one-piece connector unit, and in particular, the luer end, of the present invention is integral and ready to be used for its intended purpose. Thus, when using the presently claimed invention, some of the steps required in the above-described prior art (as shown in Figures 1A-C) can be eliminated. In particular, the step of attaching a second, separately provided cannula or other piercing member in order to convert the luer end into a usable piercing end is eliminated. In that regard, new claim 14 is being added. New claim 14 recites a one-piece ready-to-use connector with an integrated luer end. It recites many of the features of pending claim 8, but does not recite covers.

Applicants respectfully traverse the finality of the Office Action and the Examiner's position that Applicants' previous amendment necessitated the new grounds of rejection. Inasmuch as the rejection based on the combination of Crawford and Dudar is one of first impression, Applicants request that the finality of the rejection be withdrawn and that this amendment be entered.

Consequently, Applicants respectfully submit that for at least the above-cited reasons, amended Claim 8 and its respective dependent claim 11 are not anticipated or made obvious in view of the prior art. Reconsideration of the claims is respectfully requested.

Respectfully submitted,



Andrew G. Kolomayets
Registration No. 33,723
COOK, ALEX, MCFARRON, MANZO,
CUMMINGS & MEHLER, LTD.
200 West Adams Street – Suite 2850
Chicago, IL 60606
(312) 236-8500